510(k) Summary

Submitted By:

Joey Schilling, MBA
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, PO Box 489
Bloomington, IN 47402
812-339-2235

AUG - 1 2008

May 5, 2008

Device:

Trade Name:	Zilver® 635™ Biliary Stent
Proposed Classification:	Catheter, Biliary, Diagnostic

Indications for Use:

The Cook Zilver® 635™ Biliary Stent is indicated for use in palliation of malignant neoplasms in the biliary tree.

Predicate Devices:

The Zilver® 635™ Biliary Stent is similar in terms of intended use, materials of construction and technological characteristics to predicate devices reviewed as devices for palliation of malignant neoplasm in the biliary tree.

Device Description:

The Zilver® 635™ Biliary Stent is a self-expanding, nitinol stent designed for excellent radial strength and optimal longitudinal flexibility. Constructed from a series of interconnected Z-shaped segments, the stent conforms to the shape of the biliary system and provides circumferential scaffolding throughout the stent's length. Gold radiopaque markers on each end of the Zilver® 635™ Biliary Stent, along with one radiopaque marker at the distal end of the delivery system, allow precise positioning of the stent. The stent's interconnected Z-shaped segments also keep foreshortening to a minimum.

The Zilver® 635™ Biliary Stent comes preloaded in a 6 French delivery system. The stent is deployed with the use of a simple hand held device. The stent is available in unrestrained outer diameters of 4, 5, 6, 7, 8, 9 and 10 mm and in lengths of 20, 30, 40, 50, 60 and 80 mm. The 100, 120, and 140 mm length stents are an addition to this product line.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the predicate devices currently marketed and distributed by Cook Incorporated. This device will undergo sterilization similar to the predicate devices currently marketed and distributed. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.

Test Data:

The Zilver® 635™ Biliary Stent was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Deployment
   a. Profile
   b. Deployment accuracy
   c. Stent length and change due to deployment
   d. Stent diameter
   e. Uniformity of expansion
   f. Stent integrity

2. Radial force

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a biliary stent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2008

Joey Schilling, MBA, EMT-P
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, PO Box 489
BLOOMINGTON IN 47402-0489

Re: K080037
Trade/Device Name: Zilver® 635™ Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: July 25, 2008
Received: July 28, 2008

Dear Mr. Schilling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Lucile Y. Nichols DMD. FOR DR. TILLMAN

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K080037

Device Name: Zilver® 635™ Biliary Stent System

FDA's Statement of the Indications for Use for device:

The Zilver® 635™ Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080037